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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,101	02/13/2006	Toshihiro Mori	06491217PUS1	7811

2292 7590 05/16/2007
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EXAMINER	
WILDER, CYNTHIA B	
ART UNIT	PAPER NUMBER
1637	

NOTIFICATION DATE	DELIVERY MODE
05/16/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

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Office Action Summary	Application No.	Applicant(s)	
	10/568,101	MORI ET AL.	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *35 and 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's preliminary amendment filed on 2/13/2006 is acknowledged and has been entered.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-34, drawn to a method of isolating and purifying nucleic acid.

Group II, claim(s) 35, drawn to a reagent kit.

Group III, claim(s) 36, drawn to an apparatus.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The inventions of Groups I-III lack the same or corresponding special technical feature because the broadest first named invention, namely, the reagent kit as described in Group II is not "special" and does not provide a contribution over the prior art (see Muller et al., US 6084091, July 2000). Additionally, the different invention does not correspond to the same special technical feature because the different inventions have different structural properties, different function and/or use. For example, the method of Group I utilizes a solid phase for isolating and purifying nucleic acid in a sample, whereas the product of Group II is drawn to a reagent kit which can be used for commercial sales and the product of Group III is drawn to an apparatus which can be used for detecting a target. Searching the inventions of Groups I-III would constitute a serious search burden to the Examiner because the searches of the inventions of Groups I-III are not coextensive. Specifically, the searches are not coextensive because each of the inventions of Group I-III can function irrespective of the other invention. Likewise the different inventions of Groups I-III comprise non-overlapping subject matter.

3. During a telephone conversation with Mark Weiner on April 19, 2007 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-34. Affirmation of this election must be made by applicant in replying to this Office action. Claims 35-36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon applications filed in Japan on 09/2003, 12/2003 and 03/2004. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the United States application was filed more than twelve months thereafter. Applicant is afforded the instant filing date of 02/13/2006.

Information disclosure Statement

The information disclosure statement (IDS) filed on 02/13/2006 is acknowledged. However, the foreign patent documents recited on the form 1449 were not considered because an English Language translation of the foreign documents could not be found. For consideration of the references, a translation of the foreign documents must be

submitted. The IDS will remain in the application until a translation of documents has been provided.

Claim Rejections - 35 USC § 102(b)

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 8, 10-11, 23, 27, 30, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Woodard (US 5405951, April 11, 1995). Regarding claim 1, Woodward teaches a method for isolating and purifying a nucleic acid, comprising the step of: (1) contacting a sample solution containing nucleic acid to a solid phase to adsorb the nucleic acid onto the solid phase (page col. 2, line 35 to col. 3, line 8); (2) contacting a washing solution to the solid phase to wash the solid phase in such a state that the nucleic acid is adsorbed (col. 3, line 9-14); and (3) contacting an elution solution to the solid phase to desorb the nucleic acid (col. 3, lines 15-37), wherein the sample solution containing nucleic acid contains an antifoaming agent (see col. 5, which discusses the addition of polyethylene glycol (PEG), glycerol or the addition of alcohols). Theses are examples of antifoaming agents.

Regarding claim 2, Woodward teaches wherein the sample solution containing nucleic acid is prepared by further addition and mixing of a pretreatment solution containing a buffer (col. 2, lines 53-56).

Regarding claim 3, Woodward teaches wherein the sample solution containing nucleic acid is prepared by further addition of a water-soluble organic solvent (see col. 5-6, Example 6 and col. 10, lines 40-62).

Regarding claim 8, Woodward teaches wherein the nucleic acid stabilizer is a chelating agent (col. 2, lines 54-56 and Example 6).

Regarding claim 10, Woodward teaches wherein the water-soluble organic solvent contains at least one selected from the group consisting of methanol, ethanol, propanol and butanol (see col. 3, lines 43-57).

Regarding claim 11, Woodward teaches wherein the solid phase is a solid phase containing silica or a derivative thereof, diatomaceous earth or alumina (col. 3, lines 58-68).

Regarding claim 23, Woodward teaches wherein the solid phase is nonporous (col. 3, lines 58-68).

Regarding claims 27 and 30 Woodward teaches a unit for isolating and purifying a nucleic acid, which has: (a) the solid phase; (b) a container having at least two openings, which houses the solid phase; and (c) an apparatus for generating the pressure difference, which is connected to one of the openings of the container (Specifically, Woodward teaches the use of a blotter which pulls liquid thorough a membrane (page 9, lines 5-15).

Regarding claim 33, Woodward teaches wherein the washing solution is a solution containing 50% ethanol for example (see col. 3, line 24).

Regarding claim 34, Woodward teaches wherein the elution solution is a solution having a salt concentration of not more the 0.5 mol/L (col. 3, lines 15-17). Therefore, Woodward meets the limitations of the claims recited above.

Claim Rejections - 35 USC § 102(b)

7. Claims 1-3, 8-13, 19-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Su (WO 97/08547, March 1997). Regarding claim 1, Su teaches a method for isolating and purifying a nucleic acid, comprising the step of: (1) contacting a sample solution containing nucleic acid to a solid phase to adsorb the nucleic acid onto the solid phase contacting a washing solution to the solid phase to wash the solid phase in such a state that the nucleic acid is adsorbed; and (3) contacting an elution solution to the solid phase to desorb the nucleic acid, wherein the sample solution containing nucleic acid contains an antifoaming agent (see pages 3-10 and especially page 10 which teaches the addition of polyethylene glycol, which is an example of an anti-foaming agent).

Regarding claims 2, 8 and 9, Su teaches wherein the sample solution containing nucleic acid is prepared by further addition and mixing of a pretreatment solution containing a nucleic acid stabilizer, wherein said stabilizer is a chelating agent (EDTA), and wherein said wherein said stabilizer is a chelating agent, chaotropic agent, a protease or a buffer (pages 9-10, Example 1).

Regarding claim 3, 10, Su teaches Woodward teaches wherein the sample solution containing nucleic acid is prepared by further addition of a water-soluble organic solvent, such as ethanol, isopropanol or acetone (page 10, lines 8 and 9).

Regarding claim 11, Su teaches wherein the solid phase is a solid phase containing silica (col. 11, line 18).

Regarding claims 12-13, Su teaches wherein the solid phase is a solid phase containing an organic macromolecule, wherein said organic molecule has a polysaccharide structure (col. 7, line 8).

Regarding claim 19-22, Su teaches wherein the solid phase is a porous membrane having an average pore diameter of 1 to 100 microns in diameter (page 7, lines 1-100).

Regarding claim 23, Su teaches wherein the solid phase is nonporous (page 25, line 6 and 7).

Regarding claim 24 and 25, Su teaches wherein the solid phase is coated beads and wherein said beads are magnetic beads (page 25, lines 5-7).

Regarding claim 26, Su teaches wherein the adsorption and desorption of nucleic acids are carried out using a cartridge for isolating and purifying a nucleic acid, which houses the solid phase in a container having at least two openings (col. 25 and section entitled "Apparatuses of the Invention" at pages 41-46).

Regarding claim 27 and 28, Su teaches wherein the adsorption and desorption of nucleic acid are carried out using a unit for isolating and purifying a nucleic acid, which has a solid phase, a container having at least two opening which house the solid phase and an apparatus for generating the pressure different, which is connected to one of the openings of the container (page 11-12 and section entitled "Apparatuses of the Invention" at pages 41-46).

Claim Rejections - 35 USC § 102 (a) and 35 USC 102(e)

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-4, 9-24 and 26-34 are rejected under 35 U.S.C. 102(a) and 35 U.S.C. 102(e) as being anticipated by Iwaki (US 2005/00112656, publication date May 26, 2005/ filing date October 28, 2004). Regarding claim 1, Iwaki teaches a method for isolating and purifying a nucleic acid, comprising the step of: (1) contacting a sample solution containing nucleic acid to a solid phase to adsorb the nucleic acid onto the solid phase; (2) contacting a washing solution to the solid phase to wash the solid phase in such a state that the nucleic acid is adsorbed; and (3) contacting an elution solution to

the solid phase to desorb the nucleic acid, wherein the sample solution containing nucleic acid contains an antifoaming agent (paragraph 0011-0016, 0100-0102).

Regarding claim 2, Iwaki teaches wherein the sample solution containing nucleic acid is prepared by further addition and mixing of a pretreatment solution containing at least one selected from the group consisting of chaotropic salt, stabilizer, a buffer, and a protease (0071-0082).

Regarding claim 3, Iwaki teaches wherein the sample solution containing nucleic acid is prepared by further addition of a water-soluble organic solvent (0095).

Regarding claim 4, Iwaki teaches wherein the antifoaming agent contains at least one of a silicon type antifoaming agent and an alcohol type antifoaming agent (0100 and 0101).

Regarding claim 9, Iwaki teaches wherein the chaotropic agent is a guanidium salt (0090).

Regarding claim 10, Iwaki teaches wherein the water-soluble organic solvent contains at least one selected from the group consisting of methanol, ethanol, propanol and butanol (0095).

Regarding claim 11, Iwaki teaches wherein the solid phase is a solid phase containing silica or a derivative thereof (0007 and 0139).

Regarding claim 12, Iwaki teaches wherein the solid phase containing an organic macromolecule (0110 and 0205).

Regarding claim 13, Iwaki teaches wherein the organic macromolecule is an organic macromolecule having a polysaccharide (0110 and 0205).

Regarding claim 14, Iwaki teaches wherein the organic macromolecule is acetylcellulose (0137).

Regarding claim 15, Iwaki teaches wherein the organic macromolecule is an organic macromolecule where acetylcellulose or a mixture of acetylcellulose having different acetyl values is subjected to a saponification treatment (0138, 0142-0143).

Regarding claim 16, Iwaki teaches wherein degree of saponification of the organic macromolecule prepared by a saponification treatment of the mixture of acetylcelluloses having different acetyl values is 5% or more (0143).

Regarding claim 17, Iwaki teaches wherein degree of saponification of the organic macromolecule prepared by a saponification treatment of the mixture of acetylcellulose having different acetyl values is 10% or more (0126, 0138 and 0143).

Regarding claim 18, Iwaki teaches wherein the organic macromolecule is a regenerated cellulose (0128).

Regarding claims 19 and 20, Iwaki teaches wherein the solid phase is a porous membrane in which the front and backsides are asymmetric (0054 and 0147).

Regarding claim 21, Iwaki teaches wherein the porous membrane is a porous membrane having an average pore diameter of 0.9 to 5 μm (0146).

Regarding claim 22, Iwaki teaches wherein the porous membrane is a porous membrane having a thickness of 10 to 500 μm (0145).

Regarding claim 23, Iwaki teaches wherein the solid phase is nonporous (0205).

Regarding claim 24, Iwaki teaches wherein the solid phase is coated beads (0205).

Regarding claim 26, Iwaki teaches wherein the adsorption and desorption of nucleic acid are carried out using a cartridge for isolating and purifying a nucleic acid, which houses the solid phase in a container having at least two openings (0061 and 0157, 0159-0163).

Regarding claims 27 and 30 Iwaki teaches a unit for isolating and purifying a nucleic acid, which has: (a) the solid phase; (b) a container having at least two openings, which houses the solid phase; and (c) an apparatus for generating the pressure difference, which is connected to one of the openings of the container (0159-0163).

Regarding claim 28, Iwaki teaches wherein the apparatus for generating the pressure difference is an apparatus for pressurization (0105 and 0163).

Regarding claim 29, Iwaki teaches wherein the apparatus for generating the pressure difference is an apparatus for pressure reduction (0066).

Regarding claim 31, Iwaki teaches the method for isolating and purifying a nucleic acid according to claim 27, which comprises the step of: (2a) preparing a

sample solution containing nucleic acid from a sample and infusing the sample solution containing nucleic acid into one of the openings of the container housing the solid phase, the container having at least two openings; (2b) making the inner area of the container into a pressurized state by using the apparatus for generating the pressure difference being connected to the one of the openings of the container and contacting the infused sample solution containing nucleic acid to the solid phase by discharging the sample solution from another opening of the container to adsorb nucleic acid onto the solid phase; (2c) detaching the apparatus for generating the pressure difference from the one opening of the container and infusing a washing solution into the one opening of the container; (2d) making the inner area of the container into a pressurized state by using the apparatus for generating the pressure difference being connected to one of the openings of the container and discharging the infused washing solution from another opening of the container to contact the washing solution to the solid phase to wash the solid phase; (2e) detaching the apparatus for generating the pressure difference from the one opening of the container and infusing an elution solution into the one opening of the container; and (2f) making the inner area of the container into a pressurized state by using the apparatus for generating the pressure difference being connected to the one of the openings of the container and discharging the infused elution solution from another opening of the container to desorb the adsorbed nucleic acid from the solid phase and discharge nucleic acid outside the container (0163, 0188, 0202-0203, 0217-0219).

Regarding claim 32, Iwaki teaches the method according to claim 31, which comprises, before the step of (2e), (2d') contacting a solution of DNase to the solid phase and then washing the solid phase with the washing solution (0099).

Regarding claim 33, Iwaki teaches wherein the washing solution is a solution containing 20 to 100% by mass of methanol, ethanol, isopropanol or n-propanol (0173).

Regarding claim 34, Iwaki teaches wherein the elution solution is a solution having a salt concentration of not more the 0.5 mol/L (0090 and 0175). Therefore, Iwaki teaches the limitations of the instant invention.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2 and 4-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woodward as previously applied and Su (5,804,684, September 1998) and further in view of Kappel et al (20040259162, effective filing date May 2, 2003) and Sigma data Sheet, (www.sigmaaldrich.com/sigma/product%20information%20sheet/A6707pis.pdf, 12/2005, pages 1-3). Regarding claims 1, 2, and 4, Woodward teaches a method for isolating and purifying a nucleic acid, comprising the step of: (1) contacting a sample solution containing nucleic acid to a solid phase to adsorb the nucleic acid onto the solid phase; (2) contacting a washing solution to the solid phase to wash the solid phase in such a state that the nucleic acid is adsorbed and (3) contacting an elution solution to the solid phase to desorb the nucleic acid. Woodward further teach wherein PEG or glycerol and/or alcohols is added to the nucleic acid. These are examples of an antifoaming agent.

In a method similar to that of Woodward, Su teaches isolating and purifying a nucleic acid, comprising contacting a sample solution containing a nucleic acid to a solid phase in such a state that the nucleic acid is absorbed and contacting an elution solution to the solid phase to desorb the nucleic acid (see example 1, col. 10).

Neither Woodward nor Su teach wherein the antifoaming agent is a silicon type antifoaming agent.

Kappel et al teach a method and apparatus for solid phase lysis and capture of nucleic acids. Kappel teach wherein a lytic reagent is added to cells to extract the

nucleic acid, said reagent comprises may comprise a chaotropic agent, buffer, bulking agent, process enzymes, enzymatic inhibitors or an antifoaming agent, wherein said antifoaming agent include antifoam A, antifoam B and antifoam C, which are all silicon-based antifoaming agents (see attached product data sheet at page 2 for antifoam information (0109). Kappel teaches that the antifoaming agent is added to prevent excessive foaming or frothing during lysis (0117).

Therefore, one of ordinary skill in the art at the time of the claimed invention would have been motivated to have encompass antifoaming agents as those taught by Kappel in the isolation and purification methods of Woodward and Su for the obvious benefit of preventing excessive foaming or frothing as taught by Kappel.

Regarding claims 5 and 8, Su et al teach wherein the stabilizer is a chelating agent at a concentration of 10 mM (col. 10, Example 1).

Regarding claims 5-7, Su et al teach wherein the stabilizer is a reducing agent such as a mercapto compound (DTT) at a concentration of 25 mM (col. 10, Example 1).

Regarding claim 9, Kappel et al teach wherein the chaotropic agent is a guanidium salt (0116).

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of co pending application 10974681 in view of Kappel as previously applied above.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claim 1 of the instant invention and the claims 1 of copending application '681 are broadly drawn to isolating and purifying nucleic acid by

absorbing the nucleic acid to a solid phase and desorbing the nucleic acid from the solid phase and recovering the nucleic acid.

The claim 1 of copending application '681 only differs from the instant invention in that it does not recite wherein the nucleic acid comprises an antifoaming agent.

Kappel et al teach a method and apparatus for solid phase lysis and capture of nucleic acids. Kappel teach wherein a lytic reagent is added to cells to extract the nucleic acid, said reagent comprises may comprise a chaotropic agent, buffer, bulking agent, process enzymes, enzymatic inhibitors or an antifoaming agent, wherein said antifoaming agent include antifoam A, antifoam B and antifoam C (0109). Kappel teaches that the antifoaming agent is added to prevent excessive foaming or frothing during lysis (0117).

Therefore, one of ordinary skill in the art at the time of the claimed invention would have been motivated to have encompass antifoaming agents as those taught by Kappel in the isolation and purification methods for the obvious benefit of preventing excessive foaming or frothing as taught by Kappel.

This is a provisional obviousness-type double patenting rejection.

14. Claims 1-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-38 of copending Application No. 10209336 in view of Kappel as previously applied above.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claim 1-34 of the instant invention and the claims 1-38 of copending application '336 are broadly drawn to isolating and purifying nucleic acid by absorbing the nucleic acid to a solid phase and desorbing the nucleic acid from the solid phase and recovering the nucleic acid. The claims are drawn to saponification treatment (see instant claims 15-17) and also to a unit and cartridge for use in isolating and purifying the nucleic acid.

The claims 1-38 of copending application '336 only differs from the instant invention in that they does not recite wherein the nucleic acid comprises an antifoaming agent.

Kappel et al teach a method and apparatus for solid phase lysis and capture of nucleic acids. Kappel teach wherein a lytic reagent is added to cells to extract the nucleic acid, said reagent comprises may comprise a chaotropic agent, buffer, bulking agent, process enzymes, enzymatic inhibitors or an antifoaming agent, wherein said

antifoaming agent include antifoam A, antifoam B and antifoam C (0109). Kappel teaches that the antifoaming agent is added to prevent excessive foaming or frothing during lysis (0117).

Therefore, one of ordinary skill in the art at the time of the claimed invention would have been motivated to have encompass antifoaming agents as those taught by Kappel in the isolation and purification methods for the obvious benefit of preventing excessive foaming or frothing as taught by Kappel.

This is a provisional obviousness-type double patenting rejection.

15. Claims 1, 26 and 27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 10305110 in view of Kappel as previously applied above.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claim 1, 26 and 27 of the instant invention and the claims 1-3 of copending application '110 are broadly drawn to isolating and purifying

nucleic acid by absorbing the nucleic acid to a solid phase and desorbing the nucleic acid from the solid phase and recovering the nucleic acid. The claims are also drawn to a unit for use in isolating and purifying the nucleic acid.

The claims 1-3 of copending application '110 only differs from the instant invention in that they does not recite wherein the nucleic acid comprises an antifoaming agent.

Kappel et al teach a method and apparatus for solid phase lysis and capture of nucleic acids. Kappel teach wherein a lytic reagent is added to cells to extract the nucleic acid, said reagent comprises may comprise a chaotropic agent, buffer, bulking agent, process enzymes, enzymatic inhibitors or an antifoaming agent, wherein said antifoaming agent include antifoam A, antifoam B and antifoam C (0109). Kappel teaches that the antifoaming agent is added to prevent excessive foaming or frothing during lysis (0117).

Therefore, one of ordinary skill in the art at the time of the claimed invention would have been motivated to have encompass antifoaming agents as those taught by Kappel in the isolation and purification methods for the obvious benefit of preventing excessive foaming or frothing as taught by Kappel.

This is a provisional obviousness-type double patenting rejection.

16. Claims 1 and 22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 of copending Application No. 10621329 in view of Kappel as previously applied above.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claim 1 and 22 of the instant invention and the claims 1 of copending application '329 are broadly drawn to isolating and purifying nucleic acid by absorbing the nucleic acid to a solid phase and desorbing the nucleic acid from the solid phase and recovering the nucleic acid. The claims are also drawn to the thickness of the membrane (see instant claim 22).

The claim 1 of copending application '329 only differs from the instant invention in that they does not recite wherein the nucleic acid comprises an antifoaming agent.

Kappel et al teach a method and apparatus for solid phase lysis and capture of nucleic acids. Kappel teach wherein a lytic reagent is added to cells to extract the nucleic acid, said reagent comprises may comprise a chaotropic agent, buffer, bulking

agent, process enzymes, enzymatic inhibitors or an antifoaming agent, wherein said antifoaming agent include antifoam A, antifoam B and antifoam C (0109). Kappel teaches that the antifoaming agent is added to prevent excessive foaming or frothing during lysis (0117).

Therefore, one of ordinary skill in the art at the time of the claimed invention would have been motivated to have encompass antifoaming agents as those taught by Kappel in the isolation and purification methods for the obvious benefit of preventing excessive foaming or frothing as taught by Kappel.

This is a provisional obviousness-type double patenting rejection.

17. Claims 1-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 10/621715 in view of Kappel as previously applied above.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claim 1-34 of the instant invention and the claims 1-

19 of copending application '715 are broadly drawn to isolating and purifying nucleic acid by absorbing the nucleic acid to a solid phase and desorbing the nucleic acid from the solid phase and recovering the nucleic acid and saponification treatment (instant claims 15-17). The claims are also drawn to a unit and cartridge for use in isolating and purifying the nucleic acid.

The claims 1-19 of copending application '715 only differs from the instant invention in that they does not recite wherein the nucleic acid comprises an antifoaming agent.

Kappel et al teach a method and apparatus for solid phase lysis and capture of nucleic acids. Kappel teach wherein a lytic reagent is added to cells to extract the nucleic acid, said reagent comprises may comprise a chaotropic agent, buffer, bulking agent, process enzymes, enzymatic inhibitors or an antifoaming agent, wherein said antifoaming agent include antifoam A, antifoam B and antifoam C (0109). Kappel teaches that the antifoaming agent is added to prevent excessive foaming or frothing during lysis (0117).

Therefore, one of ordinary skill in the art at the time of the claimed invention would have been motivated to have encompass antifoaming agents as those taught by Kappel in the isolation and purification methods for the obvious benefit of preventing excessive foaming or frothing as taught by Kappel.

This is a provisional obviousness-type double patenting rejection.

18. Claims 1-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36 of copending Application No. 10974681 in view of Kappel as previously applied above.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claim 1-34 of the instant invention and the claims 1-36 of copending application '681 are broadly drawn to isolating and purifying nucleic acid by absorbing the nucleic acid to a solid phase and desorbing the nucleic acid from the solid phase and recovering the nucleic acid. The claims are also drawn to a unit and cartridge for use in isolating and purifying the nucleic acid, saponification treatment and the use of regenerated cellulose.

The claims 1-36 of copending application '681 only differs from the instant invention in that they does not recite wherein the nucleic acid comprises an antifoaming agent.

Kappel et al teach a method and apparatus for solid phase lysis and capture of nucleic acids. Kappel teach wherein a lytic reagent is added to cells to extract the nucleic acid, said reagent comprises may comprise a chaotropic agent, buffer, bulking agent, process enzymes, enzymatic inhibitors or an antifoaming agent, wherein said antifoaming agent include antifoam A, antifoam B and antifoam C (0109). Kappel teaches that the antifoaming agent is added to prevent excessive foaming or frothing during lysis (0117).

Therefore, one of ordinary skill in the art at the time of the claimed invention would have been motivated to have encompass antifoaming agents as those taught by Kappel in the isolation and purification methods for the obvious benefit of preventing excessive foaming or frothing as taught by Kappel.
This is a provisional obviousness-type double patenting rejection.

19. Claims 1-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 10-17 of copending Application No. 11217339 in view of Kappel as previously applied above.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claim 1-34 of the instant invention and the claims 1-5 and 10-15 of copending application '339 are broadly drawn to isolating and purifying nucleic acid by absorbing the nucleic acid to a solid phase and desorbing the nucleic acid from the solid phase and recovering the nucleic acid.

The claims 1-5 and 10-17 of copending application '339 only differs from the instant invention in that they does not recite wherein the nucleic acid comprises an antifoaming agent.

Kappel et al teach a method and apparatus for solid phase lysis and capture of nucleic acids. Kappel teach wherein a lytic reagent is added to cells to extract the nucleic acid, said reagent comprises may comprise a chaotropic agent, buffer, bulking agent, process enzymes, enzymatic inhibitors or an antifoaming agent, wherein said antifoaming agent include antifoam A, antifoam B and antiform C (0109). Kappel teaches that the antifoaming agent is added to prevent excessive foaming or frothing during lysis (0117).

Therefore, one of ordinary skill in the art at the time of the claimed invention would have been motivated to have encompass antifoaming agents as those taught by Kappel in the isolation and purification methods for the obvious benefit of preventing excessive foaming or frothing as taught by Kappel.

This is a provisional obviousness-type double patenting rejection.

20. Claims 1-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-35 of copending Application No. 10975469 in view of Kappel as previously applied above.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claim 1-34 of the instant invention and the claims 1-35 of copending application '469 are broadly drawn to isolating and purifying nucleic acid by absorbing the nucleic acid to a solid phase and desorbing the nucleic acid from the solid phase and recovering the nucleic acid. The claims are also drawn to a unit and cartridge for use in isolating and purifying the nucleic acid.

The claims 1-35 of copending application '469 differs from the instant invention in that they does not recite wherein the nucleic acid comprises an antifoaming agent.

Kappel et al teach a method and apparatus for solid phase lysis and capture of nucleic acids. Kappel teach wherein a lytic reagent is added to cells to extract the nucleic acid, said reagent comprises may comprise a chaotropic agent, buffer, bulking agent, process enzymes, enzymatic inhibitors or an antifoaming agent, wherein said antifoaming agent include antifoam A, antifoam B and antiform C (0109). Kappel teaches that the antifoaming agent is added to prevent excessive foaming or frothing during lysis (0117).

Therefore, one of ordinary skill in the art at the time of the claimed invention would have been motivated to have encompass antifoaming agents as those taught by Kappel in the isolation and purification methods for the obvious benefit of preventing excessive foaming or frothing as taught by Kappel.

This is a provisional obviousness-type double patenting rejection.

21. Claims 26-31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 of copending Application No. 10932138 in view of Kappel as previously applied above.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claim of the instant invention 26-31 and the claim 1 of copending application "138 are drawn to isolating and purifying nucleic acid by absorbing the nucleic acid to a solid phase and desorbing the nucleic acid from the solid phase and recovering the nucleic acid, wherein a unit and/or cartridge is use to carry out the method of isolating and purifying the nucleic acid.

The claim 1 of copending application '138 differs from the instant invention in that they does not recite wherein the nucleic acid comprises an antifoaming agent.

Kappel et al teach a method and apparatus for solid phase lysis and capture of nucleic acids. Kappel teach wherein a lytic reagent is added to cells to extract the nucleic acid, said reagent comprises may comprise a chaotropic agent, buffer, bulking agent, process enzymes, enzymatic inhibitors or an antifoaming agent, wherein said antifoaming agent include antifoam A, antifoam B and antiform C (0109). Kappel teaches that the antifoaming agent is added to prevent excessive foaming or frothing during lysis (0117).

Therefore, one of ordinary skill in the art at the time of the claimed invention would have been motivated to have encompass antifoaming agents as those taught by Kappel in the isolation and purification methods for the obvious benefit of preventing excessive foaming or frothing as taught by Kappel.

This is a provisional obviousness-type double patenting rejection.

Conclusion

24. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1637

5/10/2007